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[Counsel continued below]

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

MUTUAL PHARMACEUTICAL COMPANY, INC., et al.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., et al.,

Defendants.

FILED UNDER SEAL

Civil Action No. 09-5421(GEB)(TJB)

DECLARATION OF NISHAN KOTTAHACHCHI IN SUPPORT OF PLAINTIFFS' OPPOSITION TO THE MOTION FOR SUMMARY JUDGMENT FILED BY DEFENDANT WEST-WARD PHARMACEUTICAL CORP.

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- I, Nishan Kottahachchi, declare and state as follows:
- 1. I am an attorney licensed to practice law in the State of California and the District of Columbia, and am admitted *pro hac vice* in this matter before this Court. I am an associate in the law firm of Cooley LLP, attorneys of record in this matter for Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding, Inc. (collectively "Plaintiffs"). I have personal knowledge of the facts set forth in this Declaration, and if called upon to testify I could and would testify competently thereto.
- 2. Attached hereto as Exhibit A is a true and correct copy of a page from the United States Food and Drug Administration ("FDA") website titled *Guidance for FDA staff and Industry: Marketed Unapproved Drugs—Compliance Policy Guide*, publicly available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070290.pdf, and last viewed on August 20, 2010.
- 3. Attached hereto as Exhibit B is a true and correct copy of the FDA warning letter to Sunrise Pharmaceutical, Inc., publicly available on the FDA's website at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm197966.htm and last viewed on August 20, 2010.
- 4. Attached hereto as Exhibit C is a true and correct copy of the FDA's warning letter to Concord Laboratories, Inc., publicly available on the FDA's website at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075988. httm and last viewed on August 20, 2010.
- 5. Attached hereto as Exhibit D is a true and correct copy of the FDA's warning letter to Defendant Vision Pharma LLC, publicly available on the FDA's website at

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm212242.htm and last viewed on August 20, 2010.

- 6. Attached hereto as Exhibit E is a true and correct copy of a page from the FDA website titled *National Drug Code Directory*, publicly available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm, and last viewed on August 20, 2010.
- 7. Attached hereto as Exhibit F is a true and correct copy of a page from the FDA's website titled *FDA Acts to Improve Drug Safety and Quality*, publicly available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm1086 http://www.fda.gov/NewsFvents/Newsroom/PressAnnouncements/2006/ucm1086 http://www.fda.gov/NewsFvents/Newsroom/PressAnnouncements/Newsroom/PressAnnouncements/2006/ucm1086 http://www.fda.gov/NewsFvents/Newsroom/PressAnnouncements/Newsroom/PressAnnouncements/2006/ucm1086 http://www.fda.gov/NewsFvents/Newsroom/PressAnnouncements/http://www.fda.gov/NewsFvents/Newsroom/PressAnnouncements/<a href=
- 8. Attached hereto as Exhibit G is a true and correct copy of a page from the FDA's website titled *Questions and Answers About FDA's Enforcement Action Against Unapproved Injectable Colchicine Products*, publicly available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Enforceme http://www.fda.gov/Drugs/guidanceComplianceRegulatoryInformation/EnforcementActionsonUnapprovedDrugs/ucm119642.

 http://www.fda.gov/Drugs/guidanceComplianceRegulatoryInformation/EnforcementActionsonUnapprovedDrugs/ucm119642.

 <a href="http://www.fda.gov/Dru
- 9. Attached hereto as Exhibit H is a true and correct copy of Defendant West-Ward Pharmaceutical Corp.'s Responses and Objections to Plaintiff Mutual Pharmaceutical Company, Inc.'s First Set of Requests for Admission.
- 10. Attached hereto as Exhibit I is a true and correct copy of the Objections and Responses of Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. to Defendant West-Ward Pharmaceutical Corp.'s First Set of Requests for Admission.
- 11. Attached hereto as Exhibit J is a true and correct copy of Plaintiff Mutual Pharmaceutical Company, Inc.'s Objections and Responses to Defendant West-Ward Pharmaceutical Corp.'s First Set of Interrogatories.

12. Attached hereto as Exhibit K is a true and correct copy of Second Supplemental Responses of Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. to Defendant West-Ward Pharmaceutical Corp.'s First Set of Interrogatories.



16. Attached hereto as Exhibit O is a true and correct copy of a page from the FDA website titled *Single-Ingredient Oral Colchicine Video*, publicly available at

http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211975.htm, and last viewed on August 23, 2010.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed at Washington, District of Columbia on August 23, 2010.

/s/ Nishan Kottahachchi